State of New Jersey
DEPARTMENT OF HEALTH AND SENIOR SERVICES
PO BOX 360
TRENTON, N.J. 08625-0360

JON S. CORZINE
Governor

www.nj.gov/health

FRED M. JACOBS, M.D., J.D.
Commissioner

NEW JERSEY DEPARTMENT OF HEALTH & SENIOR SERVICES HUMAN RESEARCH ETHICS PROGRAM

POLICY
PROTECTION OF HUMAN RESEARCH SUBJECTS [HREP-POL-001v01]

I. PURPOSE

To set New Jersey Department of Health & Senior Services ("Department") policy for the protection of human research subjects pursuant to the Department's Federalwide Assurance (FWA-4020) with the U.S. Department of Health and Human Services. This policy shall be interpreted in good faith and in conformance with applicable New Jersey and Federal laws and regulations, including the Federal regulations for the protection of human subjects at 45 CFR Part 46, Subparts A- D.

II. APPLICABILITY

This policy and subsequent policies, procedures, forms and guidance shall apply when the Department becomes engaged in human subjects research. The Department becomes engaged in human subjects research when i) Department employees or agents a) interact or intervene with human research subjects or b) obtain human research subjects' identifiable private information, ii) the Department funds, sponsors or regulates human subjects research or iii) the Department otherwise supports human subjects research through the provision of identifiable private information or the use of Department facilities, premises or property.

III. AUTHORITY

A. Under the authority of the Commissioner, the Department's Human Research Ethics Program will implement this policy and maintain oversight authority to monitor for compliance, and implement and oversee corrective actions to address non-compliance.

B. The Commissioner serves as the FWA-designated Signatory Official.

C. The Director, Human Research Ethics Program serves as the FWA-designated Human Protections Administrator.

IV. DEFINITIONS

A. Agent: Agents are non-Department employees who perform Department-designated activities or exercise Department-delegated authority or responsibility.

B. Assent: Assent means a child's affirmative agreement to participate in research; mere failure to object is not be construed as assent.

C. The Belmont Report: The *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research* issued The Belmont Report in 1979. The report identified Beneficence, Justice and Respect for Persons as the guiding ethical principles for the conduct of biomedical and behavioral research involving human subjects.

D. Beneficence: Beneficence is the ethical obligation to secure the wellbeing of others; the corollary of which is nonmaleficence, the obligation to do no harm.

E. Conflict of Interests: A conflict of interest is any situation in which personal or professional interests may compromise or present the appearance of compromising a person's professional judgment regarding their role in human subjects research.

F. Identifiable Private Information: Information that is linked, or could be readily linked, to an individual i) pertaining to behavior that is reasonably expected not to be observed or recorded or ii) that is provided for a specific purpose for which there is a reasonable expectation of privacy.

G. Informed Consent: The legal and ethical permission given by research subjects (or their legally authorized representative) to be enrolled in research. Informed consent consists of providing information, confirming comprehension and ensuring voluntariness. Informed consent is prospective and affirmative such that "passive consent" and similar procedures are not appropriate.

H. Investigator: An individual who i) interacts or intervenes with research subjects or has access to research subjects' identifiable private information and ii) makes substantial contributions to the a) project's conception and design, b) acquisition of data or c) analysis and interpretation of data.

I. Justice: Justice is an ethical theory concerned with the fair distribution of society's benefits and burdens using allocation criteria such as equality, need, effort, societal contribution or merit.

J. Publicly Available Data: Data from which research subjects' identifiable private information cannot be ascertained.

K. Research: A systematic investigation designed to develop or contribute to generalizable knowledge.

L. Research Interaction: Activities involving interpersonal contact or communications between research subjects and investigators or research personnel.

M. Research Intervention: Procedures or manipulations of research subjects' environment to gather data (e.g., genetic tests).

N. Research Personnel: An individual who is a non-investigator member of a research team and i) interacts or intervenes with research subjects or ii) has access to research subjects' identifiable private information.

O. Respect for Persons: Respect for Persons is a moral principle that holds individuals have the right to make decisions based on their own values and preferences, and that others should respect those autonomous decisions. When an individual's autonomy is diminished due to illness, disease or injury, this principle obligates society to afford them special protections.

V. HUMAN RESEARCH ETHICS PROGRAM (HREP)

HREP is responsible for fulfilling the Department's ethical and legal obligations for the protection of research subjects. In fulfillment of this mandate HREP will:

A. Develop, implement, oversee and monitor for compliance policies, procedures, forms and guidance in fulfillment of this policy.

B. In consultation with the Commissioner and Senior Policy Advisor to the Commissioner, serve as the primary contact to Federal agencies with human subjects research oversight authority.

C. Serve as the Department's primary resource for the protection of research subjects, including assisting investigators in the development and conduct of ethically responsible research.

D. Develop and implement educational programs, projects and initiatives on the protection of research subjects.

E. In consultation with the Commissioner and Senior Policy Advisor to the Commissioner, provide program personnel to serve as the Department's Research Integrity Officer as required by the Federal regulations on research misconduct at 42 CFR Part 93.

F. Promptly report to the Commissioner, Senior Policy Advisor to the Commissioner, Institutional Review Board (IRB), Office of Legal & Regulatory Affairs and appropriate regulatory agencies if: i) research activities have been implemented or modified without IRB approval, ii) research activities have been conducted in violation of IRB decisions, determinations, directives or requirements (i.e., "serious or continuing noncompliance"), iii) research activities have been conducted in violation of Department policies or procedures, iv) research activities have been conducted in violation of Federal or New Jersey laws, regulations or guidance, v) confidentiality has been breached, vi) there has been a serious or unanticipated adverse event to a research subject, vii) there is a conflict of interests that may compromise the integrity of the research, viii) there has been a problem involving risks to subjects or others or ix) there has been a suspension or termination of IRB approval.

G. Provide advice and support to Department Divisions/Programs for the drafting of regulations, statutes, contracts, grants, and agreements that have a component related to the protection of research subjects, and review and comment on proposed human subjects research-related rules, regulations and statutes.

H. Provide guidance for the protection of human research subjects to Department personnel.

I. Conduct Ethical & Regulatory Assessments of human subjects research projects proposed under the auspices of the Department's FWA.

J. Provide support to Department Divisions/Programs responsible for data repositories and registries for the protection of research subjects' identifiable private information, with access to all data (read-only) and secured areas.

K. As mandated by the Department's FWA, maintain oversight authority for the protection of human research subjects. Such oversight includes, but may not be limited to, monitoring for compliance and implementing and overseeing corrective actions to address non-compliance based on findings from site-visits, inspections, investigations and audits of human subjects research activities, with

access to research investigators, support personnel, research-related records, documents and data, in all forms.

L. As mandated by the Department's FWA, in consultation with the Commissioner and the Senior Policy Advisor to the Commissioner, i) subject IRB-approved research to further review and approval or disapproval (HREP cannot approve research if it has not been approved by the IRB), ii) prohibit, suspend or terminate research activities, iii) prohibit investigators or support personnel from engaging in research under Department auspices or iv) take additional actions as necessary to protect the rights, welfare or privacy of research subjects.

M. Make official determinations of non-research, non-human subjects research and exempt human subjects research.

N. Make determinations for approval of death certificate requests for research purposes in accordance with New Jersey state law.

O. May establish an Advisory Council in order to solicit input and advice from Department Divisions and Programs for the protection of research subjects.

VI. INSTITUTIONAL REVIEW BOARD

The Department's IRB of record is responsible for reviewing non-exempt human subjects research to be conducted under the auspices of the Department's FWA. In fulfillment of this mandate the IRB will:

A. Develop, implement and oversee policies and procedures in fulfillment of its role and functions, including:

1. Conducting site-visits, investigations and audits of non-exempt human subjects' research with access to investigators, support personnel, research records, documents and data, in all forms; based on findings, develop, implement and oversee corrective actions.

2. Reviewing research upon initial submission and not less than yearly thereafter, reporting all actions, decisions and determinations to the investigator and HREP.

3. Ensuring proposed changes in a research activity are not initiated prior to IRB review and approval, except when necessary to eliminate apparent hazards to research subjects.

4. Determining which projects require review more often than annually and which projects needs verification from sources other than the investigator that no material changes have occurred since the previous IRB review.

5. Having the authority to approve, require modification or disapprove human subjects research.

6. Ensuring the IRB possesses appropriate knowledge of the local research context.

7. Ensuring that no IRB member participates in the initial or continuing review of human subjects research in which the member has a conflicting interest, except to provide information requested by the IRB.

8. Promptly reporting to the Commissioner, Senior Policy Advisor to the Commissioner, HREP and appropriate regulatory agencies: i) unanticipated problems involving risks to subjects or others, ii) serious or continuing noncompliance with Federal laws or regulations or IRB requirements or determinations, iii) the suspension or termination of IRB approval or iv) violations of Department policies or New Jersey laws or regulations.

9. In accordance with Federal regulations and the Department's FWA i) prohibit, suspend or terminate research activities, ii) disqualify an investigator or support personnel from engaging in research under Department auspices or iii) take additional actions to protect the rights, welfare or privacy of research subjects.

B. Function in compliance with, and only approve research conforming to, The Belmont Report, Department policies and procedures and applicable Federal and New Jersey laws and regulations, including the Federal regulations for the protection of human subjects at 45 CFR Part 46, Subparts A - D.

VII. NJDHHS RESEARCH LIAISONS

Upon receiving an extramural research proposal the Department will assign a Liaison to review the request, and provide oversight, on behalf of the Division/Program that maintains the data being requested; more than one Liaison may be utilized for the same project. In fulfillment of this mandate the Liaison will:

A. Adhere to the policies and procedures implemented by HREP for serving as a Liaison.

B. Review extramural research proposals and provide HREP with a recommendation as to whether i) the Principal Investigator is qualified to design, implement, perform, record, analyze and report the findings of the research, ii) the research is scientifically valid, iii) the identifiable private information requested is appropriate for the research and iv) the request adheres to the Department's and Division/Program's policy on Privacy & Confidentiality.

C. Contact the Principal Investigator to discuss questions or concerns raised during their review, providing the Principal Investigator the opportunity to revise their request as necessary to secure the Liaison's approval.

D. Comply with the Department's Statement of Policy on Release of Health Data, including releasing data in a secure manner such as using encrypted computer files and protected fax machines.

E. Promptly notify HREP if during the conduct of the research they determine i) research activities have been implemented or modified without IRB approval, ii) research activities have been conducted in violation of IRB decisions, determinations, directives or requirements, iii) research activities have been conducted in violation of Department policies or procedures, iv) research activities have been conducted in violation of Federal or New Jersey laws, regulations or guidance, v) confidentiality has been breached, vi) there has been a problem involving risks to subjects or others or vii) a personal or professional interest may compromise the integrity of the research.

F. When the project constitutes non-human subjects research, provide HREP-approved data and technical guidance only (so as not to cause the Department to become engaged in research).

VIII. RESEARCH INVESTIGATORS AND PERSONNEL

Investigators (e.g., principal, sub-, co-, etc.) and research personnel are ethically and legally responsible, to the extent of their involvement, for the design, implementation, performance, recording, analysis and reporting of the research.

A. The Principal Investigator is responsible for:

1. The design, implementation, performance, recording, analysis and reporting of their research, even when these activities are completed by other investigators or research personnel.

2. Screening investigators and research personnel to ensure they posses the qualifications, skills and competence to perform their assigned research duties, prior to their participation.

3. Submitting in a timely fashion IRB continuing review applications, correspondence from collaborating sites, protocol deviation reports, study termination reports and other HREP or IRB required information or documentation.

4. Obtaining IRB approval prior to implementing or modifying human subjects research.

5. Taking all reasonable precautions to protect research subjects' rights, welfare and privacy.

6. Promptly notifying HREP and the IRB if during the conduct of the research they determine i) research activities have been implemented or modified without IRB approval, ii) research activities have been conducted in violation of IRB decisions, determinations, directives or requirements, iii) research activities have been conducted in violation of Department policies or procedures, iv) research activities have been conducted in violation of Federal or New Jersey laws, regulations or guidance, v) confidentiality has been breached, vi) there has been a serious or unanticipated adverse event to a research subject or vii) a personal or professional consideration may compromise the integrity of the research.

7. Ensuring investigators and support personnel i) comply with HREP and IRB determinations, requirements, directives and decisions, ii) Department policies and procedures, iii) Federal and New Jersey laws and regulations, iv) successfully complete the Department-mandated training on the protection of research subjects prior to submitting an IRB application and v) comply with HREP and IRB reviews, site-visits, audits, investigations and inspections, including complete access to investigators, support personnel, records, documents and data, in all forms.

Fred M. Jacobs, M.D., J.D.
Commissioner

July 24, 2006
Date

Version History
Current version: v01
Previous version(s): None
Review Schedule: Annually from Date of Approval